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20350 7590 02/18/2004

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EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 02/18/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,375	03/21/2000	SUSAN MARY KINGSMAN	DYOU23.001AP	9861

TITLE OF INVENTION: TUMOR TARGETED VECTOR

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1330	\$0	\$1330	05/18/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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EXAMINER	ART UNIT	CLASS-SUBCLASS
ANGELL, JON E	1635	514-044000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1	_____
2	_____
3	_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☐ corporation or other private group entity ☐ government

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- ☐ Issue Fee
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- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

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Determination of Patent Term Extension under 35 U.S.C. 154 (b) (application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability

Application No.

09/445,375

Examiner

J. Eric Angell

Applicant(s)

KINGSMAN ET AL.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/12/03.
2. ☒ The allowed claim(s) is/are 75-77,79-90,92-100,112-116,118 and 119.
3. ☒ The drawings filed on 24 December 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

J. Eric Angell

Art Unit: 1635

DETAILED ACTION

1. This Action is in response to the communication filed on 12/12/03. Claims 75, 79, 88, 92, 99-101 and 116 have been amended and claims 78, 91, 101-111 and 117 have been cancelled as indicated in the communication filed 12/12/03. Claims 75-77, 79-90, 92-100, 112-116 and 118 are currently pending in the application and are addressed herein.

2. Prior amendments correcting the sequence compliance problems have been submitted 12/6/99, and are acknowledged.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kawai Lau on 2/5/04.

The application has been amended as follows:

Claim 87: add a comma (",") between the word "tumor" and the word "cells" in line 2.

Claim 99: replace Claim 99 with:

-- 99. A method for inhibiting the growth of a tumor in a mammal comprising delivering directly to the tumor, cells transduced ex vivo with a vector comprising a polynucleotide sequence encoding an antibody in operable linkage with a second polynucleotide sequence encoding an anti-tumor protein,

wherein said antibody and said anti-tumor protein are expressed as a fusion protein,

wherein said antibody binds 5T4 antigen on cells of said tumor, and wherein said fusion protein is expressed in an amount sufficient to inhibit the growth of said tumor. --

Art Unit: 1635

Claim 100: replace claim 100 with:

-- 100. A gene delivery system for targeting an anti-tumor gene to a tumor, wherein said gene delivery system comprises a vector comprising a first polynucleotide sequence encoding an antibody which binds 5T4 antigen on cells of a tumor and a second polynucleotide sequence encoding an anti-tumor protein,

wherein said antibody and said anti-tumor protein are expressed as a fusion protein,

wherein upon direct delivery of said vector to cells of a tumor, said fusion protein is expressed in an amount sufficient to inhibit the growth of said tumor. --

Claim 112: replace claim 112 with:

-- 112. A method of treating cancer in a mammal, comprising administering directly to a tumor in said mammal, a vector comprising one or more polynucleotide sequences encoding an antibody which binds 5T4 antigen on a tumor cell in said mammal in operable linkage with one or more polynucleotide sequences encoding a cytokine,

wherein said antibody and said cytokine are expressed as a fusion protein in a tumor cell in said mammal, thereby inhibiting growth of said tumor in said mammal. --

Claim 114: replace claim 114 with:

-- 114. A method of treating cancer in a mammal, comprising administering directly to a tumor in said mammal a cytokine and the vector of claim 75, thereby inhibiting growth of said tumor in said mammal. --

Claim 116: replace 116 with:

-- 116. A method for inhibiting the growth of a tumor in a mammal comprising delivering directly to a first cell of the tumor, a vector comprising a first polynucleotide sequence encoding an antibody in operable linkage with a second polynucleotide sequence encoding an anti-tumor protein,

wherein said antibody binds 5T4 antigen on cells of said tumor, and

wherein said fusion protein is expressed in said first cell of said tumor and wherein said fusion protein binds to 5T4 antigen on a second neighboring cell of said tumor, thereby inhibiting the growth of said tumor. --

Art Unit: 1635

Add new claim 119 as follows:

119. An expression vector comprising a first polynucleotide sequence encoding an antibody in operable linkage with a second polynucleotide sequence encoding an anti-tumor protein, wherein said antibody binds 5T4 antigen on cells of a tumor, and wherein said antibody and said anti-tumor protein are expressed as a fusion protein.

Reasons for Allowance

Considering that the previous Office Actions did not properly address the claimed vector wherein said vector expressed the antibody and the anti-tumor protein as a fusion protein, the following is an examiner's statement of reasons for allowance:

The instant claims are drawn to a vector that encodes and expresses a fusion protein wherein said fusion protein comprises an antibody that binds 5T4 antigen and an anti-tumor protein. The prior art, when considered in its entirety, generally teaches that chimeric molecules comprising an antibody which binds tumor cells and an anti-tumor molecule can be used to inhibit the growth of the tumor. However, the prior art indicates that the methods of making chimeric molecules comprising a tumor binding antibody and an anti-tumor molecule included methods wherein the chimeric molecules were typically made by chemically attaching the anti-tumor protein to the antibody (for example, see US Patent 4,997,913). Additionally, the prior art does not teach a nucleic acid sequence encoding an antibody that binds to 5T4 antigen.

Therefore, one of ordinary skill in the art would not be motivated to make and use a vector that expresses a fusion protein comprising a 5T4 antibody and an anti-tumor protein.

Art Unit: 1635


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Eric Angell, Ph.D.
Art Unit 1635



DAVE T. NGUYEN
PRIMARY EXAMINER